

In the United States Patent and Trademark Office

16248

In re application: Stable Pharmaceutical

Art Unit: 1624

Compositions

Application No.: 10/087.951

Examiner Name: Richard L.

Filed: 03/05/2002

Raymond

Inventor Name(s): Donald L. Barbeau

Docket No.: Barbeau 0302

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Amendment after First Detailed Office Action

Dear Sir:

This letter is in response to an Office Action dated January 14, 2004 from Examiner Raymond relating to the above-identified patent application. Claims 1-20, all of the elected claims pending in this application, have been rejected either under 35USC112, 35USC102 or 35USC103.

Applicant's invention relates to stable pharmaceutical formulations of hydralazine hydrochloride. Applicant submits that although hydralazine hydrochloride has been a marketed drug product for decades, it is very unstable in currently available pharmaceutical formulations. Applicant further submits that the above-identified patent application and co-pending patent application 10/306,196 filed November 27, 2002 describe and claim his invention, including a) a novel method of improving the stability of hydralazine during manufacturing and storage; b) novel pharmaceutical compositions containing stabilized hydralazine that can be administered to a patient in a delayedrelease dosage form; and c) novel hydralazine derivatives. Claims 1-20 of the present application describe a novel method of improving the stability of hydralazine during manufacturing and storage. In response to the Examiner's rejections, Applicant has amended Claims 1-20 to more particularly point out his invention and to delineate his invention over the prior art. In view of these changes, Applicant respectfully submits reconsideration and allowance of these claims.

Applicant requests that all further correspondence with this application be sent directly to the sole inventor at the following address: Donald L. Barbeau at Barbeau Pharma, Inc. 6 Williamsburg Circle, Evanston, Illinois 60203 (847)254-8532.

In the Claims:

Please substitute the flowing amended claim for pending Claim 1: